REMARKS

Claims 30-37 are pending in the application. Claims 30-32 and 34-37 are withdraw from consideration. Reconsideration of this application is respectfully requested.

I. Objections to the Specification

The Examiner has objected to the specification as not containing an abstract on a separate sheet. In response, Applicant has amended the specification to include an abstract as a separate page 53. The new Abstract is identical to the description of the Field of the Invention on page 1. Therefore, no new matter has been added in the present amendment.

II. Rejections Under 35 U.S.C. § 101

Claim 33 has been rejected as being directed to non-statutory subject matter. The Examiner alleges that claim 33 encompasses naturally occurring compounds and suggests amending the claim to recite "isolated polypeptide." This rejection is not well taken.

The Examiner's broad characterization of the fusion protein of SEQ ID NO:27 neglects to recognize the fact that the recombinant chimeric protein of SEQ ID NO:27 does not occur in nature. Follicle stimulating hormone (FSH) exists in nature as a heterodimer comprised of two non-covalently bound subunits, alpha and beta. The presently claimed protein is a fusion protein where the alpha and beta subunits of FSH are produced as a single protein chain. (See specification at page 4). Thus, claim 44 embraces statutory subject matter, since the claim clearly requires a single chain fusion protein, which is not a product of nature.

III. Rejections Under 35 U.S.C. § 103

Claim 33 has been rejected under 35 U.S.C. §103 (a) as being obvious over the following references: U.S. Patent No. 7,081,446 ("Lustbader") in view of U.S. Patent No. 5,891,855 ("Florkiewicz") and further in view of U.S. Patent No. 6,238,890 ("Boime").

Claim 33 is directed to a chimeric fusion polypeptide comprising the amino acid sequence of SEQ ID NO:27. The recombinant, chimeric, fusion polypeptide is composed of an alpha FSH

subunit fused in-frame with a beta FSH subunit. None of the cited references teaches this single chain, chimeric, fusion polypeptide.

The Examiner asserts that Lustbader teaches a synthetic chimeric FSH construct comprising an alpha FSH subunit and a beta-FSH subunit. However, The Examiner concedes that Lustbader does not disclose the chimeric polypeptide of SEQ ID NO:27.

The Examiner cites Florkiewicz for teaching an alpha-FSH subunit (SEQ ID NO:5) that is identical to amino acids 1-116 of SEQ ID NO:27 of claim 33.

The Examiner cites Biome for teaching the beta-FSH subunit (SEQ ID NO:12) that is identical to amino acids 117-227 of SEQ ID NO:27 of claim 33.

The Examiner concludes that it would have been obvious for one of ordinary skill in the art to use the method of Lustbader to construct a synthetic FSH chimeric polypeptide comprising an alpha-FSH subunit and a beta-FSH subunit taught by Florkiewicz and Boime, to allegedly arrive at a polypeptide such as SEQ ID NO:27.

Obviousness requires that each and every claim limitation be disclosed or suggested by the prior art. None of the cited references alone or in combination disclose or suggest the instant invention because they do not disclose or suggest chimeric protein comprising an alpha FSH subunit is fused in frame with the beta FSH subunit and produced as a single polypeptide chain without a linker or enhancer moiety.

In contrast, Lustbader's teachings are solely directed to chimeric FSH polypeptides containing linker segments for improved stability. Nowhere does Lustbader teach or suggest making the presently claimed fusion polypeptide where the alpha FSH subunit is fused in frame with the beta FSH subunit and produced as a single polypeptide chain without a linker or enhancer moiety. All of the chimeric polypeptides described by Lustbader contain linker or enhancer segments. Furthermore, Lustbader provides no suggestion that creating an alpha +beta FSH fusion protein without linker sequences, as reflected in the presently claimed fusion polypeptide of SEQ ID

NO:27, would be successful. Thus, Lustbader cannot provide a motivation to combine the alpha and beta FSH subunits without linker sequences. Furthermore, Lustbader provides no data with regard to the activity (reflecting expectation of success) of an alpha +beta FSH fusion protein without linker sequences.

The mere teaching of the sequences of the alpha and beta chains of FSH in Florkiewicz and Boime do not cure the deficiency of Lustbader with regard to the presently claimed fusion polypeptide.

There is no suggestion in Lustbader, Florkiewicz, or Boime to combine or even modify their products to arrive at the claimed invention encompassed by SEQ ID NO:27. Furthermore, combining Lustbader, Florkiewicz, and Boime would not produce the claimed single chain, chimeric, fusion polypeptide. Instead it would produce a chimeric, fusion polypeptide with a linker or enhancer moiety.

The Examiner is combining improperly the isolated disclosures of the cited references to reject the present claims. In combining the cited references, the Examiner fails to provide a suggestion or point to the motivation that is provided in the cited references that would have lead a skilled worker to combine the alpha and beta FSH subunits in the manner defined by the present claims. This is because the suggestion comes from the present specification, not the cited references. It is only by combining the teachings of the present specification with selected information from the prior art that the Examiner is able to synthesize reasons for rejecting the present claims under the guise of obviousness. Courts do not permit such hindsight reconstruction. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

Both the motivation to combine the relevant elements and the suggestion of success must be found in the prior art to satisfy the requirements for maintaining an obviousness rejection. *In re The Dow Chemical Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988) ("[b]oth the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure"). Finding various

elements of the claimed chimeric fusion polypeptide piecemeal in separate references is *not* sufficient motivation to combine them to arrive at a claimed invention. *In re Rouffet*, 47 USPQ2d 1453 (Fed. Cir. 1998) ("[T]he examiner must show reasons that the skilled artisan, *confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.*") (citations omitted, emphasis added).

For at least the reasons set forth above, claim 33 is not obvious over Lustbader in view of Florkiewicz and Boime. Reconsideration of claim 33 and withdrawal of this rejection under 35 U.S.C. § 103(a) is requested.

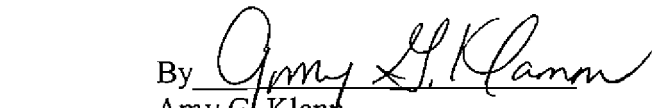
CONCLUSION

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue. Applicants reserve the right to pursue the canceled and/or non-elected subject matter in one or more continuation or divisional applications.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Dated: February 15, 2007

Respectfully submitted,

By 

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